REMARKS/ARGUMENTS

Claims 1, 2, and 4-14 have been rejected and claim 15 has been objected to. Claim 11 has been cancelled without prejudice to or disclaimer of the subject matter encompassed thereby in order to further prosecution of this application. Claims 1, 2, and 12-14 have been amended as described more fully below.

Claims 2 and 14 have been amended to remove the terms "analog" and "dimer thereof". Claim 1 has been amended to incorporate the limitation "wherein the binding sequence of the peptide component has at least a 70% amino acid sequence identity to the amino acid sequence selected from the group consisting of (1) Lys Ala Glu Tyr Lys Lys Asn Lys His Arg His (SEQ ID NO: 1); (2) Thr Thr Arg Leu Thr Arg Lys Arg Gly Leu Lys (SEQ ID NO: 2); and (3) Arg Leu Thr Arg Lys Arg Gly Leu Lys (SEQ ID NO: 8)." Claims 12 and 13 have been amended to replace "an Apo B protein binding sequence" with "the amino acid sequence selected from the group consisting of (1) Lys Ala Glu Tyr Lys Lys Asn Lys His Arg His (SEQ ID NO: 1); (2) Thr Thr Arg Leu Thr Arg Lys Arg Gly Leu Lys (SEQ ID NO: 2); and (3) Arg Leu Thr Arg Lys Arg Gly Leu Lys (SEQ ID NO: 8)." Support for these claim amendments may be found in former claim 11 and in claim 14. Accordingly, no new matter has been introduced by way of these claim amendments.

Claims 1, 2, and 4-10 and 12-15 are currently under examination in the application. Reconsideration of the claims is respectfully requested in view of the claim amendments described above and the following remarks. The Examiner's comments in the Office Action dated March 22, 2007 are addressed below in the order set forth therein.

The Rejections Under 35 U.S.C § 112, First Paragraph, Should Be Withdrawn

Response to Rejections for Lack of Written Description

Claims 1-2 and 4-14 have been rejected under 35 U.S.C. 112, First Paragraph, as "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention" (see page 3 of the Office Action dated March 22, 2007). This rejection is respectfully traversed for the reasons provided below.

The Examiner's rejection is based on the argument that claim 1 does not set forth a structure for the peptide and that the claims therefore encompass a large variable genus of peptides. The Examiner notes that claim 14 recites a structure but that "[c]laim 14 is included in the rejection as the claim is also directed to 'a dimer thereof' of the sequences recited in the claims" (see page 3 of the Office Action). As described above, claim 1 has been amended to incorporate the structural features of both claim 14 and former claim 11, but without reference to "dimers thereof". The remaining claims depend from and incorporate the limitations of claim 1.

Under the "Guidelines for Examination of Patent Applications Under 35 U.S.C. 112, ¶1, 'Written Description' Requirement" (hereinafter "the Guidelines"), a genus may be described by "sufficient description of a representative number of species . . . or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or chemical properties." 66 Fed. Reg. 1099-1111, 1106 (January 5, 2001). As amended, the present claims define a number of structural limitations for the peptide component of the claimed lipoprotein particles. In particular, the peptide component of the present claims is from 8 to 500 amino acid residues long and comprises a binding sequence having at least a 70%, 80%, 90%, or 100% amino acid sequence identity to an amino acid sequence selected from the group consisting of sequences (1), (2), or (3) (corresponding to SEQ ID NOS: 1, 2, and 8, respectively). Each of these sequences are clearly described within the specification (see, e.g., pages 9 to 11 of the specification). Applicants submit that these structural features are clearly sufficient to satisfy the requirement for written description under the Guidelines.

In view of the remarks provided above, Applicants submit that the Examiner's rejection under 35 U.S.C. § 112, First Paragraph (written description), has been overcome and should be withdrawn.

Response to Rejections for Lack of Enablement

Claims 1-2 and 4-14 have been rejected under 35 U.S.C. 112, First Paragraph, "because the specification, while being enabling for the peptides set forth in SEQ ID NOS: 3, 4, 5, 6, 7 and

9 does not reasonably provide enablement for any peptide component thereof having [an] Apo B binding site." (see page 5 of the Office Action dated March 22, 2007). This rejection is respectfully traversed as applied to the currently amended claims for the reasons provided below.

The Examiner's rejection focuses on enablement with respect to the peptide component of the claimed lipoprotein particles. The test for enablement is whether one reasonably skilled in the art could make or use the invention based on Applicants' disclosures coupled with information known in the art without undue experimentation. *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). As acknowledged by the Examiner, factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) the breadth of the claims; 2) the nature of the invention; 3) the state of the prior art; 4) the level of one of ordinary skill; 5) the level of predictability in the art; 6) the amount of direction provided by the inventor; 7) the existence of working examples; and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

As described above, the claims have been amended such that the peptide component of the present claims is from 8 to 500 amino acid residues long and comprises a binding sequence having at least 70%, 80%, 90%, or 100% amino acid sequence identity to amino acid sequence (1), (2), or (3). The specification teaches on pages 10 and 11 that the peptide component may be from 8 to 500 amino acid residues long and comprise the sequences (1), (2), and (3) or sequences having at least 70%, 80%, or 90% identity to sequences (1), (2), or (3). Furthermore, the specification provides guidance on page 11 as to conservative amino acid substitutions, deletions, and/or replacements that can be made without interfering with the ability of the amino acid sequence to bind to a binding site and elicit a physiological response. The specification further provides experimental details and data using peptides A-D and F in LDL particles, which are exemplary peptide components of the invention that encompass sequence (2) (peptides C, D, and F) and sequence (3) (peptides A and B) (see, e.g., Figure 7 and Examples 1 to 4 on pages 21 to 49). Based on such guidance in the present specification, the skilled artisan could readily

choose among possible sequence modifications to produce variant peptide components within the parameters set forth in the claims without undue experimentation.

The Federal Circuit has repeatedly stated that enablement is not precluded by the necessity for some experimentation and that a considerable amount of experimentation is permissible if it is merely routine or if the specification provides a reasonable amount of guidance as to how the experimentation should proceed. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). In the instant case, the quantity of experimentation required to determine peptides that may be used within the currently amended claims amounts to screening for peptides that are from 8 to 500 amino acid residues long, that bind to an Apo B protein receptor, and that comprise a binding sequence having at least 70%, 80%, 90%, or 100% amino acid sequence identity to amino acid sequence (1), (2), or (3). Ample guidance with respect to such experimentation has been presented in the specification as described above, including description of sequences (1), (2), or (3), exemplary peptides comprising these sequences, and conservative amino acid substitutions that may be made to such sequences while retaining Apo B binding activity. One of skill in the art would appreciate that these techniques are merely routine and the specification provides ample guidance as to how the experimentation should proceed.

Applicants note that the Examiner states on page 6 of the Office Action that "[t]he state of the prior art provides evidence for the high degree of unpredictability" with respect to amino acid changes that may be made within the peptide sequences encompassed by the claims while conserving the desired activity. However, the Examiner has not indicated which prior art documents provide evidence in support of this unsubstantiated claim. "[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of §112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support … it is incumbent upon the Patent Office … to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367,

369 (CCPA 1971) (emphasis in original). Such evidence has not been provided by the Examiner.

Finally, with respect to the use of percent identity language within the claims as amended, for the reasons provided above, Applicants submit that the specification provides adequate enabling disclosure commensurate in scope with such claims. In light of such enabling disclosure, Applicants should not be disadvantaged by a potential competitor using the information in the patent to make minor modifications to the sequences while maintaining ApoB receptor competency. One of skill in the art will understand that the listed sequences are relatively short, and that conservative substitutions could easily be made and tested without any undue burden as described above. With respect to the three particular sequences recited in the current claims, the sweeping statements made by the Examiner on pages 6 and 7 of the Office Action regarding predictability of protein function for any Apo B binding sequence, are no longer applicable.

In view of the remarks provided above, Applicants submit that the Examiner's rejection under 35 U.S.C. § 112, First Paragraph (enablement), has been overcome and should be withdrawn.

The Objection to the Claims Should Be Withdrawn

The Examiner objected to claim 14 for use of the phrase "or dimer thereof", and objected to claim 15 as being dependent upon rejected base claim 1. As described above, claim 14 has been amended to remove the phrase "or dimer thereof". In addition, for the reasons provided above, Applicants believe that the amendment to claim 1 has placed this claim in allowable form. Accordingly, these objections have been obviated and Applicants request that they be withdrawn.

CONCLUSION

In view of the aforementioned amendments and remarks, Applicants respectfully submit that the objections to the claims have been obviated, and that the rejections of the claims under 35 U.S.C. 112, First Paragraph, are overcome. Accordingly, Applicants submit that this application is now in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required. However, in the event that extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 C.F.R. §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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